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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,899	12/13/2001	Max Schaldach	7163-34	1956
21324	7590	10/02/2003	EXAMINER	
HAHN LOESER & PARKS, LLP TWIN OAKS ESTATE 1225 W. MARKET STREET AKRON, OH 44313			MICHENER, JENNIFER KOLB	
			ART UNIT	PAPER NUMBER
			1762	10

DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 10/021,899		Applicant(s) SCHALDACH ET AL.	
Examiner Jennifer Kolb Michener		Art Unit 1762	

-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10 and 16-28 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) 11-15 and 29-36 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>8, 9</u> | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 11-15 and 30-36, drawn to a stent, classified in class 623, subclass 1.
 - II. Claims 1-10 and 16-29, drawn to a method, classified in class 427, subclass 2.24.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different method such as applying the marker material in a pre-hardened state.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

Art Unit: 1762

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
6. This application contains claims directed to the following patentably distinct species of the claimed invention: Figures 4A, 4B, 4C, 4C, and 5.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 11 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. During a telephone conversation with Steve Grant on 4/15/2003 a provisional election was made with traverse to prosecute the invention of the method, claims 1-10 and 16-29. Affirmation of this election must be made by applicant in replying to this Office action. Claims 11-15 and 30-36 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

9. Claim 1 is objected to because of the following informalities: there is no closed bracket, "]" to indicate the end of the deleted portions of the claim. For the purposes of examination, Examiner has interpreted the claim to be exclusive of the material from the open bracket "[" to the end of the claim as the entirety of this subject matter is redundant when taken in light of the added claim language. Correction is required so that printing of the claim, at the time of allowance, will be correct.

Appropriate correction is required.

Examiner's Suggestions/Interpretations

10. In claims 2, 3, and 10, Applicant amended claims, in some cases, to change active method steps, such as pouring and sintering, to adjectives for describing materials, such as "flowable", "pourable", "sinterable", or cold-setting. Examiner notes that these claims do not necessarily require pouring or sintering, etc. If Applicant intends to claim a method step of pouring or sintering or the like, Examiner suggests the use of active method steps to that effect.

11. In claims 4, 6, 16, and 21-24, the phrases "joined and in particular welded" and "irradiation...in particular with laser" are used. Because these claims contain a broad limitation, followed by a narrower limitation, Examiner has interpreted these claims to require the broad limitation, with the narrower limitations being merely exemplary, with the claims not necessarily limited thereto.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1, 2, 4-6, 10, 17, 19, 21, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Boatman et al. 5,632,771.

Boatman teaches a method of applying a marker element to an implant, such as a stent, which has a main body and eyelets (41, 42), i.e., openings in said main body for

Art Unit: 1762

receiving the marker element. Radiopaque marker elements are heated in place in the eyelets. The marker elements are "hardenable" as required by Applicant. Upon cooling, the gold or platinum, both of which are solid at room temperature, inherently hardens therein, forming a cold-set. (abstract, Figure 1, col. 7, lines 48-55).

Regarding claim 2, melted gold or platinum is pourable or flowable.

Regarding claim 4, the marker elements are joined to the stent.

Regarding claims 5, 6, 17, 19, 21, 23 the heating step occurs "in place" which is local application or absorption of heat by the marker, qualifying as "endothermic".

14. Claims 1, 2, and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Berry (WO 99/15108).

Berry teaches a method of applying a marker element to an implant, such as a stent, which has a main body and an eyelet, i.e., opening in said main body, for receiving the marker element. Berry teaches melting gold or other radiopaque material into the eyelet. The melted marker elements are "hardenable". Upon cooling, the gold, which is solid at room temperature, inherently hardens therein, forming a cold-set. (abstract, Figure, page 31).

Regarding claim 2, melted gold is pourable or flowable.

Regarding claim 4, the marker elements are joined to the stent.

Art Unit: 1762

15. Claims 1-2, 4-6, 10, 17, 19, 21, 23, and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Globerman (WO 97/33534).

Globerman teaches a method of applying a marker element to an implant, such as a stent, which has a main body with openings therein for receiving the marker element. Compression and/or heating of the marker material welds or fuses the marker into the opening. The marker elements, such as gold, are hardenable" as required by Applicant. Upon cooling, the gold, which is solid at room temperature, inherently hardens therein, forming a cold-set (abstract, Figures, page 4, lines 20-22, 26, page 6, lines 10-15).

Regarding claim 2, melted gold is pourable or flowable.

Regarding claim 4, the marker elements are joined to the stent.

Regarding claims 5, 6, 17, 19, 21, 23 the heating step occurs "in place" with local application of a laser, causing absorption of heat by the marker, qualifying as "endothermic".

Regarding claim 29, Globerman teaches the use of a heat treatment so that gold from the marker and stainless steel from the stent body will migrate into one another causing a matrix combination of the two (page 6-page 7). This combination enters the openings and hardens therein, as required by claim 1 and meets the limitation of an "amalgam", or mixture, as required by claim 29.

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

18. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

19. Claims 3, 16, 18, 20, 22, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boatman in view of Hossainy (US 6,379,381).

Boatman teaches that which is disclosed above regarding the melting of radiopaque markers into the eyelets or openings of a stent. What Boatman fails to teach is the use of powder markers.

Hossainy teaches a method of filling depots or openings in a stent structure with radiopaque marker elements by dissolving particulate markers, such as gold, in solution for application into the openings (abstract; col. 11, lines 10-15).

Since Boatman teaches the use of melting to render gold markers flowable to fill an eyelet opening of a stent and Hossainy teaches the application of such markers in solution, which is also flowable for ease of filling the depot openings, Hossainy would have reasonably suggested the use of powder markers in the method of Boatman. It would have been obvious to one of ordinary skill in the art to use the teachings of Hossainy in the method of Boatman to provide Boatman with an alternative method of rendering the markers flowable for filling of the eyelet openings within the stent.

The marker is joined to the stent, as required by claim 16.

Both Hossainy and Boatman heat the stent, Hossainy to evaporate solvent and Boatman to melt the marker locally, both of which qualify as endothermic, as required by claims 18, 20, 22 and 24.

20. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Globerman.

Art Unit: 1762

Globerman teaches that which is disclosed above regarding welding gold marker to metallic stents, but fails to specifically teach the use of a current flow in applying the weld energy. However, it is Examiner's position that it is well-known in the art to use electric resistance welding when it is desired to join two pieces of metal. Resistance welding involves forcing electric current to flow as required by Applicant in claim 8. It would have been obvious to one of ordinary skill in the art to select resistance welding for use in the welding operation of Globerman with the expectation of successful results since such welding is useful in joining two metals, as is the case in Globerman. Resistance welding inherently uses a flow of current.

21. Claims 7, 25, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Globerman in view of Braun et al. (6,162,244)

Globerman teaches that which is disclosed above regarding welding the marker elements into openings of a stent. What Globerman fails to teach is the use of ultrasonic welding.

Braun et al. teaches the use of ultrasonic welding for fusing metallic filament suitable on stent filaments/struts (col. 3, line 4).

Since Globerman teaches welding metallic marker elements to metallic stent struts and Globerman teaches the suitability of *ultrasonic* welding in metallic stent welding operations, Braun would have reasonably suggested the use of ultrasonic welding in the welding operation of Globerman. It would have been obvious to one of ordinary skill in

Art Unit: 1762

the art to use the teachings of Braun in the method of Globerman to provide Globerman with a welding method suitable for metallic stents.

22. Claims 26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boatman in view of Hossainy as applied to claims 3, 16, 18, 20, 22, and 24 above, and further in view of Braun.

Boatman teaches the use of heat to fuse marker elements within openings of a stent.

The use of heat to attach metals qualifies as welding. What Boatman in view of

Hossainy fails to teach is the use of *ultrasonic* welding as the welding method. Braun is

cited for those reasons outlined above. It would have been obvious to one of ordinary

skill in the art to use the teachings of Braun in the method of Boatman in view of

Hossainy to provide Boatman with a welding method suitable for metallic stents.

Allowable Subject Matter

23. Claim 9 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art of record fails to teach a hardening step effected by galvanic deposit for hardening marker elements within openings in implantable medical devices.

Conclusion

24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb Michener whose telephone number is 703-306-5462. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 703-308-2333. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.



Jennifer Kolb Michener
Patent Examiner
Technology Center 1700
September 22, 2003